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March 23, 2021

***VIA ECF***

Honorable Robert Kugler, U.S.D.J.
U.S. District Court - District of New Jersey
Mitchell S. Cohen Building & US Courthouse
1 John F. Gerry Plaza, Courtroom 4D
4th and Cooper Streets
Camden, New Jersey 08101

Honorable Thomas I. Vanaskie (Ret.)
Special Master
Stevens & Lee
1500 Market St., East Tower, Suite 1800
Philadelphia, Pennsylvania 19103-7360

Re: ***In re Valsartan, Losartan, and Irbesartan Liability Litigation*, Case No. 1:19-md-02875-RBK (D.N.J.)**

Dear Judge Kugler and Judge Vanaskie:

Please accept this letter on behalf of the Plaintiffs in advance of the March 24, 2021 Discovery Hearing and Case Management Conference.

Plaintiffs continue to confront significant production deficiencies from the Defendants. This needs to be seen in perspective to illustrate the substantial prejudice this is causing the Plaintiffs. In early 2020, Judge Schneider granted significant extensions to the manufacturer Defendants to make their productions, pushing their outside deadline for their rolling productions to November 30, 2020. (Ex. A hereto). Thereafter, once the productions began in July 2020, Plaintiffs repeatedly voiced their concerns that the productions were not compliant, at virtually

every conference for the balance of the year. Defendants scoffed at Plaintiffs, and at every turn represented that the productions were on schedule and would be completed as ordered. Judge Schneider accepted these representations. Ultimately, on December 19, 2020, Judge Schneider confronted these Defendants, and Teva, ZHP, Mylan, Aurobindo, and Hetero represented, on the record, that the productions were substantially complete at the end of November 2020, as ordered. (12/09/2020 Tr. 18:11-21, 18:22-19:5, 19:7-20:7, 20:22-21:5, 21:8-21:16, Ex. B hereto). Torrent's counsel was not asked, but they remained silent and said nothing about any issues with their production. (12/09/2020 Tr. 17-21).

It has been proven that these representations were not based in fact. When the depositions were to begin, the Defendants finally acknowledged the material deficiencies in their productions and requested an extension of the period set to conduct fact depositions so they could bring their productions into compliance before the depositions began. Yet, even that extension has not cured the problem. Plaintiffs continue to expend significant resources policing the productions and engaging in distracting meet and confers and submissions to the Court in pursuit of documents and information that was required to be produced last year. To be clear, the production issues were intended to be addressed last year, but the Defendants' representations were accepted by the Court, and Plaintiffs were required to accept them as well. Now, instead of being able to focus their attention on the conduct of depositions, and preparation of expert reports, Plaintiffs are forced to fight ongoing battles in an effort to obtain the documents and information, and in some cases ESI compliant metadata, that should have been produced last year. This prejudice is compounded by the Defendants' over-designation of documents as privileged or otherwise inappropriately withheld, which is another massive source of distraction that is playing out. Whether this was

Defendants' plan, or they are in some instances simply incapable of making compliant productions, the result is the same. Massive distraction and prejudice to Plaintiffs.

**1. Hetero Discovery Status**

The Court is well aware of the ongoing saga of the Hetero production deficiencies. The parties submitted status letters to the Court on March 16, 2021. (See Plaintiffs' Hetero Status Letter at Exhibit H). The problems are as basic as missing and incorrect metadata, and as material as the failure to produce key protocols and SOP's, and testing documents. Hetero's counsel continues to represent that it is working with its vendor and its client to get answers to basic questions and figure out what is missing and when it will be produced. In fact, despite multiple requests and Hetero's agreement to do so, Hetero has not produced a list of the applications, databases, sharepoints, and other central document and data locations that contained the relevant documents and data, and to confirm all have been produced. This is a basic step that was required to take place at the outset, before documents were collected. In addition, to the extent missing documents are being produced, they are limited to some of those identified as examples of missing documents by Plaintiffs – this is of great concern since it is certain that Plaintiffs are incapable of identifying all missing documents due to the fact that they do not know the full extent of what exists.

At this point, the situation is dire. Although Hetero continues to make partial, incomplete productions of items, Hetero's counsel appears to be incapable of identifying and producing all responsive documents and information, and basic questions continue to be answered with the refrain that counsel continues to consult with its vendor and client to get answers. The reason for this state of affairs is far less important than its continued existence. How much more distracting effort must Plaintiffs expend on essentially doing Hetero's job in identifying deficiencies in the

production, rather than focusing all resources on preparation for the depositions? How many more times will depositions need to be adjourned? Plaintiffs need to be able to move forward with the depositions, confident that all responsive documents and information have been produced in ESI compliant form, or a litigation sanction precluding Hetero from defending on the merits will need to be entered. The alternative is quite imperfect (as demonstrated by the Aurobindo and Mylan sections below) – Plaintiffs proceed with the depositions as Hetero continues to work out its issues, and depositions are held open for continuation as the documents and information continues to be produced. And it is likely that in this scenario, the depositions will demonstrate further production deficiencies on an ongoing basis, as is occurring with other Defendants. The prejudice from this ongoing situation is palpable and needs to be eliminated.

**2. Aurobindo Discovery Deficiencies**

**A. Unsearched Sources of Data**

Aurobindo's document production was due to be completed by November 2020. After that date, Plaintiffs repeatedly questioned Aurobindo on the size of its production and asked (in many different ways) why the productions were so small. Each time these questions were asked, Plaintiffs were reassured by Aurobindo's counsel on the record that Aurobindo's responses to Plaintiffs' Rule 34 Requests were complete and that Aurobindo had complied with its obligations. *See e.g.,* 02/17/2021 Tr. 31:23-35:3; 03/10/2021 Tr. 77:6-82:19.

Despite repeatedly reassuring both Plaintiffs and the Court that Aurobindo had complied with its discovery obligations, Plaintiffs discovered during the deposition of one of Aurobindo's witnesses, Bhadresh Doshi, that there were a minimum of four shared drives (S, X, M, and W) used by the witness in the course of his work on valsartan that were never searched during the

course of Aurobindo's productions. Mr. Doshi also testified that much of his work consisted of entering in and retrieving data from noncustodial sources, such as Trackwise, Oracle, LIMS, and QAMS. Mr. Doshi also testified that he kept paper notebooks that were never produced, and he further testified that all valsartan batch records from 2015-2017 were maintained in paper copy. Mr. Doshi also testified that he would also download documents onto his hard drive and that he used Microsoft office for his work. Nonetheless, Plaintiffs' review of the metadata of the custodial files produced for Mr. Doshi revealed that the *only* source of data for these documents was Mr. Doshi's email. Either none of the other sources of data were ever searched, or if they were, no documents from these sources were produced to Plaintiffs.

Aurobindo has since volunteered only to search the S drive, despite Plaintiffs requesting that productions be made from all of the above sources. Aurobindo notified Plaintiffs that is intends to make additional productions from the S drive concerning a number of custodians, one of whom (Prasad Gorijavolu) is due to be deposed on Thursday, March 25, 2021 (the day after the Discovery Conference).

Plaintiffs further requested copies of the notes Mr. Doshi was referring to in his deposition and have also yet to receive those or even a commitment to produce them.

Now that depositions are underway, Plaintiffs are discovering more and more sources of data that are clearly integral to the work performed by the custodians in this case, and it is clear that Aurobindo's discovery strategy consists of waiting to be caught before it undertakes a true search of both custodial and noncustodial data sources.

Plaintiffs therefore request that the Court order Aurobindo to do the following:

1. Complete production of all additional documents from the S drive no later than Tuesday, March 30, 2021;

2. Search all other drives mentioned by Mr. Doshi in his deposition (i.e., the X, M, and W drives) and produce documents no later than Friday, April 2, 2021; and

3. Provide Plaintiffs with a list of all non-custodial sources of data it searched to respond to Plaintiffs' Rule 34 Requests.

**B. Aurobindo's Hard Drives**

Plaintiffs remain at a loss for why Aurobindo and its vendor chose to mail empty hard drives to India, wait for the hard drives to be loaded, and then ask that the hard drives be mailed back to the United States. *See* ECF 1038. Plaintiffs' understanding, based upon the FedEx updates provided by Aurobindo, is that these hard drives have not even reached Aurobindo's headquarters yet. This problem seems to be compounded by the fact that, according to ECF 1038-1, Aurobindo "requested non-express clearance." This is untenable, given the discovery schedule and the number of documents Aurobindo claims it needs to review.

Aurobindo has a number of options for transferring data to the United States:

**Option 1:** Aurobindo can purchase a Dropbox account for $20 per month, that allows for up to 2 Terabytes of data. Aurobindo can encrypt its data, add it to Dropbox, and provide access to its ediscovery vendor in the United States.

**Option 2:** Aurobindo can transfer its data via FTP. If Aurobindo has approximately 1 million documents (which would be startling, considering Aurobindo Pharma Ltd. had only produced about 16,000 documents as of the December production deadline), and assuming that on average, a document is 10 pages, that would equal approximately 10 million pages, or 200 GB of data. Assuming conservatively that the transfer rate was only 100 megabits per second, which is

roughly 1/5 of the speed many Americans have in their homes, this data transfer would take only 4.5 hours.

Aurobindo should not be permitted to continue flouting this Court's discovery schedule by using the mail to delay its receipt of data. Plaintiffs request that the Court compel Aurobindo to transfer the data using one of the options above (or one that can similarly be accomplished in a day) to meet its production deadlines so that all parties can complete depositions on time.

**C. Aurobindo Purchases from ZHP**

[redacted]

[redacted]

**D. Missing Standard Operating Procedures**

Plaintiffs have now had a chance to review the SOP productions and note that there are a number of SOPs missing. Additionally, many of the SOPs that were produced were missing versions in place during the Relevant Time Period (i.e., when Aurobindo was researching or making valsartan). Plaintiffs have asked Aurobindo to supplement this production, but Aurobindo has not yet done so. Plaintiffs further provided Aurobindo with a list of Standard Operating Procedures that appear relevant but that have not yet been produced. Plaintiffs therefore request that the Court compel Aurobindo to produce the following Standard Operating Procedures and to supplement its current production to ensure Plaintiffs have the Standard Operating Procedures that were in place during the Relevant Time Period.

Below is the list of missing Standard Operating Procedures:

**Aurobindo Pharma Ltd. Missing SOPs**

**Missing from APL Corporate QA SOPs:**

1. Technology Transfer & New Product Validation
2. Data integrity monitoring
3. To introduce new SOP for analytical method validation
4. Identification and Reporting of Unknown peaks In Gas Chromatography and Chromatography Hyphenated with Mass Spectrometry analysis

5. Procedure For Conducting Photo Stability Study
6. Product Quality Review
7. Management Review Of The Pharmaceutical Quality System
8. Preparation and Handling of Stability Study Trend Charts for Active Pharmaceutical Ingredients
9. Site Master File
10. Document Control
11. Calibration of humidity chambers and cooling incubators
12. Handling of Deviations
13. Assigning Batch Number and Manufacturing Dates For Materials, Intermediates And Active Pharmaceutical Ingredients
14. Format Preparation And Numbering System

**Missing from APL Corporate QC SOPs:**

1. Chromatographic Integration Techniques
2. Handling of Laboratory Incidents
3. Qualification of Analytical Instruments and Equipment
4. Calibration of Gas Chromatograph
5. Calibration of FT-IR Spectrophotometer
6. Calibration of UV-Visible Spectrophotometer
7. Calibration of Automatic Titrators
8. Roles and Responsibilities of Quality Control Department
9. Standards Management
10. Vendor Assessment and Qualification for Laboratory Services
11. Care, Maintenance and Regeneration of Electrodes
12. Procedure for Calibration of ICP-OES Spectrometer and Microwave Sample Digester
13. Calibration of Ultra Performance Liquid Chromatography

**Missing from APL Plant QA SOPs:**

1. Good Recording Practices
2. Approach for executing Pre-Validation, validation and post Validation Batches
3. Definition for Storage Condition
4. Creation of user identification user privileges, password policy, log in and log out for document issuance software.
5. Policy on Testing by Outside Agency.
6. Training
7. Combining Leftover Fractions of Approved API
8. Online Activity Monitoring
9. Procedure For In-Process Sampling Of Centrifugation And Drying Validation.
10. Handling of Critical Process Parameters

11. Policy On Handling Of Elemental Impurities

**Missing from APL Plant QC SOPs:**

1. Analytical Reference (A.R.) Numbering System.
2. Sampling And Distribution Of Intermediate And Active Pharmaceutical Ingredients (APIs)
3. Cleaning of Laboratory, Laboratory Equipment and Quality Control Sampling Tools.
4. Quality Control Equipment Numbering System
5. Handling and Storage of Retention Samples
6. Temperature and Humidity Monitoring in Quality Control Laboratory.
7. Review of Audit Trails and Data Verification
8. Analysis and Approval of purified solvents & recovered solvents
9. Operation And Privileges Of Lab Solutions Software
10. Recording In Equipment Usage Log
11. Holding Time study of Drug intermediates And Raw materials
12. Operation & Cleaning of Sample Distribution Booth.
13. Assigning And Extension Of Retest Dates for Raw Materials, Packaging Materials, Intermediates, Recovered Solvents And Finished Products
14. Recording Flow of Quality Control Department Documents
15. Chromatographic Analysis, Documentation And Assigning Batch Numbers To Mobile Phase / Buffer Preparation.
16. Password Policy
17. Operation Of Gas Chromatograph For Head Space With Auto Injector Of Shimadzu GC-2010, GC-2010 plus Models With Lab Solution Software.

**Aurobindo USA Missing SOPs**

1. Deviations, Planned and Unplanned
2. Document control
3. Handling of Complaints Received From Regulatory Authorities
4. Handling of Customer Communication-Inquiries by Non-Pharmacovigilance Employees
5. Handling of a Facility Inspection by a Government Agency-Regulatory
6. Pharmacovigilance Department-Roles and Responsibilities
7. Pharmacovigilance Training
8. Handling of Lack of Effect Cases
9. Handling of 15-day Alert Reports
10. Handling of Post Marketed Adverse Event Reports
11. Handling of Customer Communications-Inquiries by Pharmacovigilance Employees
12. Aurobindo Field Alerts

13. FDA Visits at Aurobindo
14. QAR Aurobindo Reports
15. Performing Batch Record Review and Release of Aurobindo Lots
16. Compliance Monitoring by GPvD for APUSA PVG
17. Notification to the FDA of an illegitimate or suspect illegitimate product
18. Corporate Internal Audit Program
19. Corporate Supplier Qualification Program
20. Life Cycle Management of Regional Quality Standard
21. Creation of Approved Supplier List Reports in Oracle
22. Changing supplier status in Oracle

**Aurolife Missing SOPs**

1. Good documentation practices
2. Quality Risk Management
3. Cleaning of the sampling room
4. Cleaning & Sanitization for Compression Tooling

## II. Privilege Log Challenges

Consistent with the guidance provided in Special Master Order No. 5, Plaintiffs are now in possession of Aurobindo's cast of characters and have had a chance to evaluate its privilege log with the added knowledge of the roles of the individuals listed. (Ex. D hereto). Based upon this new information, Plaintiffs learned that only *three* individuals on the log are attorneys. To that end, Plaintiffs challenge the privilege designations of the categories of entries below:

### A. No Attorney(s) Copied on Communications:

Aurobindo claims attorney-client privilege over many documents that were not sent by or to a lawyer. It is the asserting party's burden to establish that a communication was sent for the primary purpose of requesting or rendering legal advice. *See, e.g., In re Avandia Mktg., Sales Pracs. & Prods. Liab.,* No. 07-md-01871, 2009 WL 4807253, at *9-10 (E.D. Pa. Oct. 2, 2009). Communications between non-lawyers, that do not otherwise specifically reflect a request or the provision of legal advice, cannot be withheld on the basis of attorney-client privilege. *Id.*

Aurobindo improperly invokes attorney-client privilege for many non-privileged communications between non-lawyer employees only. For instance, Auro-MDL 2875-0106022 is an email sent by one non-attorney employee to another non-attorney employee. But the log description, inconsistent with the non-lawyer status of these two employees, asserts that this is a "[d]ocument reflecting legal advice regarding recall and regulatory issues." Another entry, Auro-MDL 2875-0106282, purports to be a "[d]ocument reflecting legal advice regarding recall and regulatory issues," but the chain is only among non-lawyers, and includes individuals from a different company entirely (Shawn Gray and Jack Patterson are listed as representatives of third-party Inmar). Plaintiffs requested that Aurobindo revise the following entries to indicate whether any of the authors, senders, recipients, or copyees are attorneys who were rendering legal advice, or de-designate the entries. To date, Aurobindo has failed to respond. Plaintiffs therefore ask that the following documents be produced:

> Auro-MDL 2875-0084558, Auro-MDL 2875-0084615, Auro-MDL 2875-0087312, Auro-MDL 2875-0087370, Auro-MDL 2875-0088700, Auro-MDL 2875-0088701, Auro-MDL 2875- 0088940, Auro-MDL 2875-0088941, Auro-MDL 2875-0103844, Auro-MDL 2875-0103845, Auro-MDL 2875-0103975, Auro-MDL 2875-0103976, Auro-MDL 2875-0103977, Auro-MDL 2875-0103979, Auro-MDL 2875-0104018, Auro-MDL 2875-0104019, Auro-MDL 2875- 0104020, Auro-MDL 2875-0104021, Auro-MDL 2875-0104809, Auro-MDL 2875-0104810, Auro-MDL 2875-0104811, Auro-MDL 2875-0104812, Auro-MDL 2875-0104843, Auro-MDL 2875-0104844, Auro-MDL 2875-0104845, Auro-MDL 2875-0104877, Auro-MDL 2875- 0104914, Auro-MDL 2875-0105379, Auro-MDL 2875-0106022, Auro-MDL 2875-0106023, Auro-MDL 2875-0106024, Auro-MDL 2875-0106282, Auro-MDL 2875-0106283, Auro-MDL 2875-0106285, Auro-MDL 2875-0106286, Auro-MDL 2875-0106288, Auro-MDL 2875- 0106289, Auro-MDL 2875-0106290, Auro-MDL 2875-0106291, Auro-MDL 2875-0106292, Auro-MDL 2875-0106293, Auro-MDL 2875-0106302, Auro-MDL 2875-0106303, Auro-MDL 2875-0106304, Auro-MDL 2875-0106306, Auro-MDL 2875-0106307, Auro-MDL 2875- 0106308, Auro-MDL 2875-0106309, Auro-MDL 2875-0106329, Auro-MDL 2875-0106330, Auro-MDL 2875-0106331, Auro-MDL 2875-0106332, Auro-MDL 2875-0106333, Auro-MDL 2875-0106334, Auro-MDL 2875-0106335, Auro-MDL 2875-0106336, Auro-MDL 2875- 0106337, Auro-MDL 2875-0106445, Auro-MDL 2875-0107385, Auro-MDL 2875-0107386, Auro-MDL 2875-0107387, Auro-MDL 2875-

0107388, Auro-MDL 2875-0107389, Auro-MDL 2875-0107390, Auro-MDL 2875-0107392, Auro-MDL 2875-0107810, Auro-MDL 2875- 0107817, Auro-MDL 2875-0107818.

**B. No Attorney(s) Requesting or Rendering Legal Advice**

As discussed above, it is insufficient simply to claim blanketly that communications between non-lawyer employees are privileged because they are somehow providing information requested by an unnamed attorney who might render legal advice, or reflect legal advice rendered by some unidentified attorney at a different point in time. For instance, Auro-MDL 2875-0084558 is a communication between non-lawyers, copying non-lawyers, but is nevertheless withheld on privilege grounds. Aurobindo states that this entry is a "[d]ocument reflecting legal advice regarding regulatory issues and litigation communications," but Aurobindo does not adequately describe the attorney who provided the advice. Similarly, Auro-MDL 2875-0084615 is a "[d]ocument reflecting legal advice regarding recall issues" but the entry does not appear to include or involve any lawyers. This description provides no information about attorney involvement in the form of requesting information for the provision of legal advice, or from whom legal advice is being request. Yet another example is Auro-MDL 2875-0087312, a document without any senders or recipients listed, and authored by an individual listed as "unknown" by Aurobindo, but which Aurobindo describes as being attorney-client privileged and work product because it is a "[d]ocument reflecting legal advice regarding regulatory issues and litigation communications," without any detail about the attorney who purportedly rendered the legal advice. As another court of this District has put it "statements in [a party's] privilege logs that particular documents . . . were prepared at the request of counsel without specifically naming the requesting attorney are not helpful . . . .The Court, therefore, will . . . direct [the party] to submit a revised privilege log

specifically identifying each document's author, recipient, purpose, and, if applicable, the name of the attorney who requested the information contained in the communication." *E.I. du Pont de Nemours & Co. v. MacDermid,* 20099 WL 3048421, at *7 (D.N.J. Sept. 17, 2009). Plaintiffs requested, for each of the following entries, that Aurobindo specify in the description field the attorney rendering the legal advice purportedly reflected in the document, requesting the information to render legal advice, or to which attorney the information was being provided:

> Auro-MDL 2875-0084558, Auro-MDL 2875-0084615, Auro-MDL 2875-0087312, Auro-MDL 2875-0087370, Auro-MDL 2875-0088700, Auro-MDL 2875-0088701, Auro-MDL 2875- 0088940, Auro-MDL 2875-0088941, Auro-MDL 2875-0103844, Auro-MDL 2875-0103845, Auro-MDL 2875-0103975, Auro-MDL 2875-0103976, Auro-MDL 2875-0103977, Auro-MDL 2875-0103979, Auro-MDL 2875-0104018, Auro-MDL 2875-0104019, Auro-MDL 2875- 0104020, Auro-MDL 2875-0104021, Auro-MDL 2875-0104809, Auro-MDL 2875-0104810, Auro-MDL 2875-0104811, Auro-MDL 2875-0104812, Auro-MDL 2875-0104843, Auro-MDL 2875-0104844, Auro-MDL 2875-0104845, Auro-MDL 2875-0104877, Auro-MDL 2875- 0104914, Auro-MDL 2875-0105379, Auro-MDL 2875-0106022, Auro-MDL 2875-0106023, Auro-MDL 2875-0106024, Auro-MDL 2875-0106282, Auro-MDL 2875-0106283, Auro-MDL 2875-0106285, Auro-MDL 2875-0106286, Auro-MDL 2875-0106288, Auro-MDL 2875- 0106289, Auro-MDL 2875-0106290, Auro-MDL 2875-0106291, Auro-MDL 2875-0106292, Auro-MDL 2875-0106293, Auro-MDL 2875-0106302, Auro-MDL 2875-0106303, Auro-MDL 2875-0106304, Auro-MDL 2875-0106306, Auro-MDL 2875-0106307, Auro-MDL 2875- 0106308, Auro-MDL 2875-0106309, Auro-MDL 2875-0106329, Auro-MDL 2875-0106330, Auro-MDL 2875-0106331, Auro-MDL 2875-0106332, Auro-MDL 2875-0106333, Auro-MDL 2875-0106334, Auro-MDL 2875-0106335, Auro-MDL 2875-0106336, Auro-MDL 2875- 0106337, Auro-MDL 2875-0106445, Auro-MDL 2875-0107385, Auro-MDL 2875-0107386, Auro-MDL 2875-0107387, Auro-MDL 2875-0107388, Auro-MDL 2875-0107389, Auro-MDL 2875-0107390, Auro-MDL 2875-0107392, Auro-MDL 2875-0107810, Auro-MDL 2875- 0107817, Auro-MDL 2875-0107818.

**C. Over-Inclusion of Recipients**

Attorney-client privilege is waived if communications are disclosed to employees who did not need access to them. *SmithKline Beecham,* 232 F.R.D. at 476. Further, to be privileged, the primary purpose of a communication must be for the express purpose of seeking or rendering legal advice. *In re Avandia Mktg., Sales Pracs. & Prods. Liab.,* No. 07-md-01871, 2009 WL 4807253,

at *4 (E.D. Pa. Oct. 2, 2009). Not only does over-inclusion of recipients suggest a communication is not confidential (a prerequisite to a privilege claim), but it further suggests the primary purpose of the communication is not for seeking or rendering legal advice. For instance, an email sent to "thirteen [pharmaceutical company] employees for review, only one of whom was an attorney," cannot be said to have been sent for "the primary purpose" of obtaining or giving legal advice. *Id.* The same rule applies to attachments to emails. As but one example, sending around a draft internal Q&A document to "five other [pharmaceutical company] employees, only one of whom was an attorney," is an insufficient basis for suggesting the attachment itself is privileged as well. *Id.* Aurobindo asserts attorney-client privilege over many communications that were circulated much more broadly than would suggest they were strictly confidential or that they were primarily intended for the provision or request of legal advice.

Take for example AuroMDL 2875-0103975, which is a communication between non-attorneys copying six non-attorneys. On its face, the wide circulation of this email belies any claim of attorney-client privilege. Plaintiffs therefore request that the Court require Aurobindo to de-designate the following entries, all of which appear to be sent to five or more recipients:

> Auro-MDL 2875-0088700, Auro-MDL 2875-0088940, Auro-MDL 2875- 0103844, Auro-MDL 2875-0103975, Auro-MDL 2875-0103979, Auro-MDL 2875-0104018, Auro-MDL 2875-0104020, Auro-MDL 2875-0104809, Auro-MDL 2875-0104810, Auro-MDL 2875-0104843, Auro-MDL 2875-0107386, Auro-MDL 2875-0107388, Auro-MDL 2875- 0107810.

**D. Communications Involving Third Parties**

To be attorney-client privileged, a communication must be confidential. Communications from or to third parties vitiates confidentiality and, therefore, any claim of attorney-client privilege. *See, e.g., Munich Reinsurance Am., Inc. v. Am. Nat'l Ins Co.,* No. 09- 6435, 2011 WL 1466369, at

*18 (D.N.J. Apr. 18, 2011). The following Aurobindo log entries appear to be from or to third parties:

> Auro-MDL 2875-0087312, Auro-MDL 2875-0087370, Auro-MDL 2875-0103845, Auro-MDL 2875-0107385, Auro-MDL 2875-0107392, Auro-MDL 2875-0104812, Auro-MDL 2875-0104845, Auro-MDL 2875-0106291, Auro-MDL 2875- 0106329, Auro-MDL 2875-0106334, Auro-MDL 2875-0106331, Auro-MDL 2875-0106336, Auro-MDL 2875-0104914, Auro-MDL 2875-0106282, Auro-MDL 2875-0105490, Auro-MDL 2875-0106282, Auro-MDL 2875-0106290, Auro-MDL 2875-0103844, Auro-MDL 2875 0104018, Auro-MDL 2875-0107386, Auro-MDL 2875-0107388, Auro-MDL 2875-0106024.

Plaintiffs requested that Aurobindo de-designate or clarify whether the individuals/entities are not third parties, but Aurobindo has not responded. Plaintiffs therefore request that these documents be produced.

**E. Work Product Claims Not in Anticipation of Litigation**

It is axiomatic that a claim of attorney work product requires a showing of a specific claim of impending litigation. *See, e.g., SmithKline Beecham,* 232 F.R.D. at 483. The mere possibility of potential litigation will not satisfy the invoking party's burden. *Id.* Further, documents routinely prepared in the ordinary course of business will not be protected. *Id.* Aurobindo asserts work-product protection over many documents that do not appear to have been prepared in anticipation of a specific impending or ongoing litigation, or that appear to be nothing other than ordinary-course business documents. Work-product protection does not apply in either of these contexts. Please remove the work product privilege claims for the following documents or revise their log entries accordingly:

> Auro-MDL 2875-0088940, AuroMDL 2875-0088941, Auro-MDL 2875-0103844, Auro-MDL 2875-0103845, Auro-MDL 2875- 0103974, Auro-MDL 2875-0103975, Auro-MDL 2875-0103976, Auro-MDL 2875-0103977, Auro-MDL 2875-0103978, Auro-MDL 2875-0103979, Auro-MDL 2875-0103980, Auro-MDL 2875-0103981, Auro-MDL 2875-0103982, Auro-MDL 2875-0104010, Auro-MDL 2875- 0104018, Auro-MDL 2875-0104019, Auro-MDL

2875-0104020, Auro-MDL 2875-0104021, Auro-MDL 2875-0104809, Auro-MDL 2875-0104810, Auro-MDL 2875-0104811, Auro-MDL 2875-0104812, Auro-MDL 2875-0104843, Auro-MDL 2875-0104844, Auro-MDL 2875- 0104845, Auro-MDL 2875-0104846, Auro-MDL 2875-0104876, Auro-MDL 2875-0104877, Auro-MDL 2875-0104914, Auro-MDL 2875-0105378, Auro-MDL 2875-0105379, Auro-MDL 2875-0105490, Auro-MDL 2875-0106022, Auro-MDL 2875-0106023, Auro-MDL 2875- 0106024, Auro-MDL 2875-0106282, Auro-MDL 2875-0106283, Auro-MDL 2875-0106285, Auro-MDL 2875-0106286, Auro-MDL 2875-0106288, Auro-MDL 2875-0106289, Auro-MDL 2875-0106290, Auro-MDL 2875-0106291, Auro-MDL 2875-0106292, Auro-MDL 2875- 0106293, Auro-MDL 2875-0106302, Auro-MDL 2875-0106303, Auro-MDL 2875-0106304, Auro-MDL 2875-0106306, Auro-MDL 2875-0106307, Auro-MDL 2875-0106308, Auro-MDL 2875-0106309, Auro-MDL 2875-0106329, Auro-MDL 2875-0106330, Auro-MDL 2875- 0106331, Auro-MDL 2875-0106332, Auro-MDL 2875-0106333, Auro-MDL 2875-0106334, Auro-MDL 2875-0106335, Auro-MDL 2875-0106336, Auro-MDL 2875-0106337, Auro-MDL 2875-0106445, Auro-MDL 2875-0107385, Auro-MDL 2875-0107386, Auro-MDL 2875- 0107387, Auro-MDL 2875-0107388, Auro-MDL 2875-0107389, Auro-MDL 2875-0107390, Auro-MDL 2875-0107392, Auro-MDL 2875-0107810, Auro-MDL 2875-0107817, Auro-MDL 2875-0107818.

**F. Work Product Claims Without Attorney Involvement**

Aurobindo asserts work product protection over a number of documents that do not have any link to an attorney. Plaintiffs asked Aurobindo to de-designate the following entries, or revise the entries to indicate sufficient information to allow Plaintiffs or the Court to ascertain who the attorney is whose mental impressions are reflected in the withheld document. To date, Aurobindo has not responded. Plaintiffs therefore ask that the Court order Aurobindo to produce the following documents:

Auro-MDL 2875-0084558, AuroMDL 2875-0084615, Auro-MDL 2875-0087312, Auro-MDL 2875-0087370, Auro-MDL 2875- 0088700, Auro-MDL 2875-0088701, Auro-MDL 2875-0088940, Auro-MDL 2875-0088941, Auro-MDL 2875-0103844, Auro-MDL 2875-0103845, Auro-MDL 2875-0103975, Auro-MDL 2875-0103976, Auro-MDL 2875-0103977, Auro-MDL 2875-0103979, Auro-MDL 2875- 0104018, Auro-MDL 2875-0104019, Auro-MDL 2875-0104020, Auro-MDL 2875-0104021, Auro-MDL 2875-0104809, Auro-MDL 2875-0104810, Auro-MDL 2875-0104811, Auro-MDL 2875-0104812, Auro-MDL 2875-0104843, Auro-MDL 2875-0104844, Auro-MDL 2875- 0104845, Auro-MDL 2875-0104877, Auro-MDL 2875-0104914, Auro-MDL 2875-0105379, Auro-MDL 2875-0106022, Auro-MDL 2875-0106023, Auro-MDL 2875-0106024, Auro-MDL 2875-0106282, Auro-MDL 2875-

0106283, Auro-MDL 2875-0106285, Auro-MDL 2875- 0106286, Auro-MDL 2875-0106288, Auro-MDL 2875-0106289, Auro-MDL 2875-0106290, Auro-MDL 2875-0106291, Auro-MDL 2875-0106292, Auro-MDL 2875-0106293, Auro-MDL 2875-0106302, Auro-MDL 2875-0106303, Auro-MDL 2875-0106304, Auro-MDL 2875- 0106306, Auro-MDL 2875-0106307, Auro-MDL 2875-0106308, Auro-MDL 2875-0106309, Auro-MDL 2875-0106329, Auro-MDL 2875-0106330, Auro-MDL 2875-0106331, Auro-MDL 2875-0106332, Auro-MDL 2875-0106333, Auro-MDL 2875-0106334, Auro-MDL 2875- 0106335, Auro-MDL 2875-0106336, Auro-MDL 2875-0106337, Auro-MDL 2875-0106445, Auro-MDL 2875-0107385, Auro-MDL 2875-0107386, Auro-MDL 2875-0107387, Auro-MDL 2875-0107388, Auro-MDL 2875-0107389, Auro-MDL 2875-0107390, Auro-MDL 2875- 0107392, Auro-MDL 2875-0107810, Auro-MDL 2875-0107817, Auro-MDL 2875-0107818.

## III. Improperly Withheld Documents

Plaintiffs have attached to their agenda letter a list of 42 documents which Aurobindo has withheld on the basis of "Draft" and "Other Products." (Ex. E hereto). Plaintiffs request that Aurobindo be compelled to produce each document for the reasons specified below.

Withholding documents on the basis of "draft document" is wholly improper and without support in any federal rule or authority. Indeed, no other Defendant has dared to withhold company documents on the basis that they are "drafts." Aurobindo, however, has withheld drafts of the following documents:

- SOP-QA007.05 Equipment, Instruments and Facility Numbering System.doc
- Reduce Testing SOP-Final.DOC
- DEV-18-026.doc
- Cover letter.doc
- Valsartan Statement.doc

Aurobindo cannot claim attorney work product privilege over these documents, because Aurobindo did not disclose these documents on Aurobindo's privilege log. Furthermore, to the extent Aurobindo now attempts to claim such a privilege, these arguments have now been waived by Aurobindo's failure to include these documents on their privilege log for months.

Beyond improperly withholding "drafts" of responsive company authored documents, Aurobindo has also withheld several documents as "other products" when they appear to be responsive and relevant to the case. These include documents titled:

- API - Reduced Testing Proposals.doc
- RE FDA Inspection details and DMF status.msg
- Annexure-3.5 Training records.pdf
- 4. Aurobindo.pdf

Plaintiffs ask that all documents in the attached be produced in one week's time.

**3. Mylan Discovery Deficiencies**

Plaintiffs have been forced to postpone the third and final day of 30(b)(6) deposition testimony of Mylan's corporate designee, Derek Glover, based on revelations that surfaced during the first two days of testimony regarding critical categories of unproduced documents, some of which include core discovery that should have been produced long ago. In addition, once Mr. Glover's deposition is complete, Plaintiffs anticipate having to raise issues regarding Mr. Glover's designation in the first place. This will be addressed at the next CMC to the extent Mr. Glover does not cure a number of deficiencies Plaintiffs have identified for Mylan in his testimony on Day 3.

The lone issue for the Court at this CMC is Plaintiffs' request for documents pertaining to the FDA's inspection of Mylan's Unit 7 facility. The FDA's inspection of Mylan's Unit 7 facility yielded a number of damning observations regarding Mylan's continued disregard of the safety implications of Mylan's use of recovered solvents. Specifically, among other relevant findings to this case, the FDA found in its February 2020 inspection (and September 2020 Establishment Inspection Report ("EIR")) that Mylan failed to test its recovered solvents for impurities and failed to perform adequate evaluations of its recovered solvent suppliers. Notably, these FDA findings

did not just pertain to Mylan's generalized recovered solvent operations. **Rather, the findings regarding inadequate impurity testing were with regard to o-xylene, the very solvent Mylan's root cause investigation attributed to introducing NDEA contamination into all of Mylan's valsartan API**. And further, the FDA's observations regarding inadequate solvent vendor evaluations specifically related to Vega Life Sciences, **the very same vendor Mylan used to recover o-xylene for valsartan API at Unit 8**. As if these two connections alone were not enough to demonstrate the obvious relevancy of the documents, Mylan specifically referred the FDA to its corrective actions taken at Unit 8 arising from the valsartan API contamination in its written responses to the FDA's observations. In meet-confers with Plaintiffs' counsel, Mylan took the extraordinarily stretched position that Mylan's cGMP failures in 2020 do not bear on what occurred at Mylan's facilities leading up to the recall in late 2018. Plaintiffs adamantly disagree. If anything, the FDA's findings at Unit 7 demonstrate – two years later – Mylan's complete and continued disregard for patient safety by continuing the same neglectful practices regarding its solvent recovery operations that led to its NDEA contamination problem in the first place.

The Court should order Mylan to produce documents relating to the FDA's Unit 7 inspection as soon as possible so that Plaintiffs can question Mylan's corporate designee, Derek Glover, on them at the upcoming third day of his deposition.

**4. Defense Request for Dismissal of Louisiana Plaintiffs' Claims**

At the last status conference, Defendants raised the issue of whether Louisiana, New Jersey, and Ohio personal injury cases with claims dismissed by MTD Order No. 5 should be removed from the Bellwether trial pool on account of being "uncharacteristic" of the universe of cases filed in the MDL. At that time, Defendants suggested that on account of certain claims in

those cases being subsumed by their respective state's product liability/consumer protection statutes that the cases were not truly representative of the rest of the personal injury cases filed in the MDL where this was not an issue. Plaintiffs responded that they were afforded by court order 30 days to amend those claims on release of the final order on the Motions to Dismiss and that Plaintiffs intended to amend. The Court did not entertain the Defendants overtures to repopulate the Bellwether Pool at that time.

Now, Defendants have repackaged the same argument under the guise of a "housekeeping" measure. Defendants suggest that because the Court dismissed claims from the Louisiana cases on account of subsumption, that they should be dismissed by name, removed from the Court's docket, which would then allow Defendants to repopulate the bellwether pool. This is just another attempt by Defendants to remove cases they feel are strong Plaintiff's cases and to repopulate the pool with what they hope will be weaker cases. The Court should not allow such a calculated maneuver.

**5. Downstream Defendants' Obligations Regarding Defendant Fact Sheets**

The Defense Fact Sheets (DFS) for Pharmacy, Wholesaler, Finished Dose Manufacturer, and API Manufacturer Defendants were approved on August 6, 2020. Dkt. 546. The Court directed that Defendants only complete a DFS for a group of 20 cases to be chosen by Plaintiffs. The DFS was to be completed in stages, with Pharmacies allowed 90 days from the trigger date of August 31, 2020 to complete their DFS, and then Wholesalers allowed 60 days after the Pharmacies completion, then 60 days for Finished Dose Manufacturers, and 60 days for API Manufacturers. All told, the completion of a DFS under this staging would take 9 months to complete. While Plaintiffs are required to complete a PFS for every case, Defendants were not obligated to complete

a DFS for every case, but rather, they were only required to complete a fact sheet for the 20 cases identified in August by Plaintiffs.

Bellwether negotiations commenced in late December. The parties discussed the importance of having completed DFSs in-hand before Plaintiff depositions which led to the agreement that 10 cases selected for the pool would be chosen from the original 20 where a DFS had already been started back in August of 2020. By January 28, 2021, each of the original 10 cases should have had a completed Pharmacy and Wholesaler DFS completed (i.e., 90 days from August 31, 2020 for Pharmacy + 60 days for Wholesaler). Plaintiffs realized this had not occurred for 4 of the original 10 cases and raised the issue with Defendants. First, Plaintiffs believe that the retailers that were identified in the PFS for the 20 cases were required to complete the DFS, regardless of whether they were a named-party for those 20 cases, and that these DFSs should have completed the pharmacy DFSs. Plaintiffs request that Pharmacies for these bellwether cases be ordered to complete these DFSs within 7 days.

Secondly, the Wholesaler Defendants' response was that because the Plaintiffs had not sued a pharmacy in those 4 cases and since the retailer did not fulfill their requirement to complete a DFS, then the Wholesalers Defendants were under no obligation to complete a DFS. In other words, since the Wholesaler Defendants had not received information from the Pharmacy DFS identifying which wholesaler sold product to the Pharmacy, Wholesaler Defendants assert they have no requirement to complete a DFS. Instead, Wholesaler Defendants suggest that Bellwether Plaintiffs should, at this stage, waste valuable time and resources to third-party subpoena the information directly from the Pharmacy, and then provide the information obtained to the Wholesaler Defendants.

This is unacceptable to Plaintiffs. Each of these 4 plaintiffs have identified the NDC code of the drug they took and the pharmacy where the drug was purchased in Section I.C. of their Plaintiff Fact Sheet. The Wholesaler Defendants—of which there are only 3 (AmerisourceBergen, Cardinal Health, and McKesson)—admit that this is all the information they need to search their client's database and to complete a DFS yet they are unwilling to do so for these 4 cases. Again, Plaintiffs are not asking the Wholesaler Defendants to perform this task across the all cases filed in the MDL. Rather, only the 4 cases in the original 10 bellwethers where this issue has arisen, and any of the remaining 18 bellwether cases where this issue may also arise. Plaintiffs even offered to memorialize this agreement in writing with the Wholesaler Defendants, yet they refused. Plaintiffs therefore ask the Court to order the Wholesaler Defendants to complete a DFS for each of the Bellwether cases and not wait for Pharmacies to complete their DFSs. Plaintiffs request that Wholesalers for these bellwether cases be ordered to complete their DFSs within 7 days.

The remaining issue with respect to the DFSs concerns the time for completion of the DFS. When the parties negotiated, and the Court subsequently approved the DFS, it was not contemplated that a Bellwether Pool would soon be selected and that Plaintiff depositions would occur in such a compressed timeframe. This has come about at the insistence of the Defendants. Now, with Bellwether Plaintiff depositions looming, the DFSs remain incomplete. Plaintiffs need the DFSs to be completed in order to prepare for and defend the depositions. This was the basis for the inclusion of 10 bellwether pool cases from the original 20 that were identified for DFS workup back in August of 2020. Plaintiffs have requested that DFSs be completed at all levels at least 7 days prior to a Bellwether Plaintiffs deposition but have not received an answer from Defendants on whether they intend to comply with this request.

**6. Bellwether Trial Pool Order and Plaintiffs' Proposed Bellwether Trial Plan**

To date, the parties have agreed to a selection process for the Initial Bellwether pool and the parties have agreed to a timeframe whereby the 28 plaintiffs in the Initial Bellwether pool would have their depositions taken. However, the parties have major disagreements as to the scope of further discovery for bellwether cases.

Plaintiffs have provided a Bellwether Trial proposal for narrowing the Initial Bellwether pool of 28 cases to a Bellwether Trial Pool of 8 cases. On these 8 cases, Plaintiffs propose that the parties depose one treater and one prescriber for each of these 8 cases. These 8 cases would be selected as follows: 2 Joint picks (the parties each had 15 picks and 2 of the picks were jointly picked by plaintiffs and defendants), 3 plaintiff picks that would be randomly selected by the Court from the remaining 13 Initial Bellwether plaintiff picks, and 3 defense picks that would also be randomly selected by the Court from the remaining 13 Initial Bellwether defense picks. This proposal would focus further discovery on a smaller set of cases that will be worked up for trial. Plaintiffs' Bellwether Trial proposal is similar to the Bellwether protocol utilized in Benicar and many other MDLs. In Benicar, the Initial Bellwether pool consisted of 30 cases that were winnowed down to 10 cases via random selection by the Court, and then the parties took one treater and one prescriber deposition for each of the 10 cases. Even though the Benicar litigation consisted of cases with over 80 different gastrointestinal conditions with widely varying causality arguments and widely varying damages, the information learned through the Benicar bellwether pool was representative and helpful in aiding the parties in settlement negotiations. In Valsartan, Plaintiffs' Bellwether Trial proposal is fair, will likely be representative and will lead to a reasonable scope of discovery that will advance the goals of this litigation at this time.

On the other hand, despite having Plaintiffs' Bellwether Trial proposal since March 3, 2021, and despite the parties' multiple previous conversations about the need to further winnow the Initial Bellwether pool, defendants have not provided any proposal. Rather, they have simply provided objections to Plaintiffs' Bellwether Trial proposal, while continuing to request an unreasonable and unnecessary amount of bellwether depositions that serve no real purpose on advancing the case at this stage of the litigation.

Plaintiffs request guidance from the Court regarding a Bellwether Trial plan and the scope of bellwether depositions.

In addition, plaintiffs continue to disagree with defendants' continued attempts to include a dismissal/replacement clause in their proposed Initial Bellwether Order. This issue has been presented to the Court multiple times. The Court has agreed with plaintiffs' argument that it is premature to include this sort of dismissal/replacement clause, since there has not been any dismissal of any of the initial bellwether cases at this time. Furthermore, plaintiffs believe the pool needs to be further narrowed to a Bellwether Trial pool (as argued above) and any sort of replacement clause at this stage is unnecessary as there has not been a dismissal yet and these cases will need to be further narrowed to a Bellwether Trial pool anyways.

**7. Retailer and Wholesaler Discovery Update**

At the last CMC on March 10, 2021, Special Master Vanaskie directed Plaintiffs to respond to Retail Pharmacy Defendants' February 16, 2021 letter (in which they asked to "pause" discovery of them), and to follow-up separately with Wholesaler Defendants as well (who also had asked to pause discovery and, at the CMC, adopted the discovery positions set forth in Retail Pharmacy Defendants' letter). Plaintiffs sent letters to each group two days after the CMC, on March 12,

2021. See Exs. F & G. As of the morning of March 23, 2021, neither group of defendants has responded.

**8. Plaintiff Fact Sheet Show-Cause Submission**

Plaintiffs will be prepared to address any deficiencies at the Case Management Conference.

**9. Plaintiffs and Torrent's Joint Stipulation**

Plaintiffs note that Torrent filed a joint stipulation regarding the dismissal of Torrent Private and the acceptance of service of Torrent Pharmaceuticals for valsartan, losartan, and irbesartan cases on November 13, 2020. (ECF 630, Ex. I hereto). Plaintiffs respectfully ask the Court to approve this joint stipulation.

Respectfully,

ADAM M. SLATER